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Docket No.: 1489.1001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the Application of:

James E. McGowan, Jr.

Serial No. 09/826,420 Group Art Unit: 1744

Confirmation No. 5040

Filed: April 5, 2001 Examiner: CHORBAJI, MONZER R

For: MEDICAL ARTICLE STERILIZATION METHOD AND DEVICE

APPEAL BRIEF

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Final Office Action in the above-identified application, and pursuant to the Notice of Appeal filed March 29, 2005, Applicants submit this Brief with the fee of $500.00 set forth by 1.17(c).

(I) Real Party In Interest

The real party in interest in this appeal is the assignee KIMBERLY-CLARK WORLDWIDE, INC.

(II) Related Appeals and Interferences

The undersigned attorney, the appellant and the assignee know of no related appeals or interferences which would be directly affected by or directly affect or have a bearing on the Board's decision in this appeal.

(III) Status of Claims

Claims 1-36 are currently pending, claims 1-36 stand finally rejected and claims 1-36 are appealed. Claims 1-36 are each independently patentable over the prior art, as discussed in detail below, and do not stand or fall together.

(IV) Status of Amendments

No amendments have been filed subsequent to the final rejection.

(V) Summary of the Claimed Subject Matter

Many medical articles must be sterilized before they can be sold. One way to accomplish sterilization is by using a sterilizing gas, such as ethylene oxide or a mixture thereof. The application describes three sterilization processes using ethylene oxide. The first process, which is known as a chamber sterilization process, is described from page 1, line 14 through page 3, line 19. The second process is the conventional form, fill and seal process. The second process is described from page 3, line 20 through page 5, line 9. The third sterilization process relates to the present invention. The third sterilization process is a form, fill and seal process, which is improved relative to the second sterilization process. The third process is described in the application from page 5, line 11 through page 27, line 16. The third sterilization process is also shown in the drawings.

Specifically with regard to independent claims 1 and 15, a medical article may be sterilized by preheating medical articles 414/142 (see Figs. 1 and 5A-5D) in a pretreatment area 200 (see Fig. 2). Pretreatment area 200 has a heat source 250 to heat the medical article. Page 9, lines 7-20, for example, describe pretreatment. Referring to Fig. 3, a device 320 forms a housing 417 in a first web 412. Page 10, lines 12-16, for example, describe forming the housing. The medical article 142 which has been heated in the pretreatment area 200 is loaded into the housing 417 in the first web 412. See Fig. 3. The article is loaded into the housing at an article loading station 120. Page 11, lines 10-14, for example, describe loading the article. An alignment device 332 aligns a second web 416 with the first web 412. Page 12, lines 5-9, for example, describe alignment. At a sterilization sealing station 410 the first web 412 and the second web 416, with the medical article 142 loaded into the housing 417, are sterilized. Page 12, lines 9-11and page 14, line 7 through page 25, line 3, for example, describe sterilization. Figs. 5A, 7A and 7B, for example show sterilization. Then, the first and second webs 412, 416 are sealed together. Page 25, line 3 through page 26, line 13, for example, describe sealing. Figs. 5B, 7C and 7D, for example, show sealing.

Specifically with regard to independent claims 8 and 22, the sterilization-sealing station 410 may have gas injection pin 600 to inject gas into the housing 417, between the first and second webs 412, 416. Page 15, line 6 through page 16, line 8, page 18, line 22 through page 19, line 3 and page 19, line 17 through page 20, line 6, for example, describe gas injection pins. See also Figs. 5A and 7A-7D.

Specifically with regard to independent claim 33, the gas may be injected between the

first and second webs without (page 4, line 21 through page 5, line 3) a ported nozzle (see page 4, lines 1-5).

(VI) Grounds Of Rejection To Be Reviewed On Appeal

Claim 33 is rejected under 35 USC § 112, first paragraph as containing new matter. Claim 33 is also rejected under 35 USC § 112, second paragraph for indefiniteness.

Claims 1, 4-7, 15 and 18-21 are rejected under 35 USC § 103(a) as being obvious over U.S. Patent No. 5,749,203 to McGowan, Jr.

Claims 2, 3, 8-14, 16, 17 and 22-36 are rejected under 35 USC § 103(a) as being obvious over McGowan, Jr. in view of a Multivac Packaging Machines reference.

(VII) Argument

A. <u>The Law</u>

1. The Law Regarding the Specification Issues Raised by the Examiner

It is well-settled that the test for compliance with the *description* requirement is whether a person skilled in the art would reasonably conclude from the disclosure whose filing date is being relied on that the inventor had possession, as of the filing date, of the claimed invention. See, e.g., Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 U.S.P.Q. 2d 1111, 1116 (Fed.Cir. 1991) and cases discussed therein. How the disclosure accomplish this fact is unimportant. *Id.* The lack of literal basis in the specification for a negative limitation may be not be sufficient to establish a *prima facie* case for lack of descriptive support. Ex parte Parks, 30 U.S.P.Q. 2d 1234, 1236 (Board of Patent Appeals and Interferences 1993).

The initial burden of establishing a prima facie basis to deny patentability to a claimed invention on any ground is always upon the examiner. In re Oetiker, 977 F.2d 1443, 24 USPQ2d 1443 (Fed.Cir. 1992). In rejecting a claim under the first paragraph of 35 U.S.C. 112 for lack of adequate descriptive support, it is incumbent upon the examiner to establish that the originally-filed disclosure would not have reasonably conveyed to one having ordinary skill in the art that an appellant had possession of the now claimed subject matter. Wang Laboratories, Inc. v. Toshiba Corp., 993 F.2d 858, 26 USPQ2d 1767 (Fed.Cir. 1993). Adequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention. In re Herschler, 591 F.2d 693, 200 USPQ 711 (CCPA 1979); In re Edwards, 568 F.2d 1349, 196 USPQ 465 (CCPA 1978; In re Werthein, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). Rather, it

is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed. In re Anderson, 471 F.2d 1237, 176 USPQ 331 (CCPA 1973).

In Ex parte Parks, the Federal Circuit found the limitation "in the absence of a catalyst" to have adequate descriptive support (not new matter) because "[t]hroughout the discussion which would seem to cry out for a catalyst if one were used, no mention is made of a catalyst." Ex parte Parks, 30 U.S.P.Q.2d at 1236.

2. The Law Regarding the Obviousness Issues Raised by the Examiner

Under Graham v. John Deere Co.,383 U.S. 1,148 U.S.P.Q. 459 (1966) the scope and content of the prior art are to be determined, the differences between the prior art and the claims at issue are to be ascertained and the level of skill in the art is to be ascertained. Against this background the obviousness of the subject matter is determined.

Obviousness cannot be established by combining the teaching of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined only if there is some suggestion or incentive to do so. (see ACS Hospital Systems, Inc. v. Montefiore Hospital, 221 USPQ 929, 932, 933 (Fed. Cir. 1984))

The prior art must not only suggest the desirability that the teachings of references be combined but must also suggest the desirability of the modifications in the manner proposed by the Examiner as well as the results to be achieved (see Ex parte Costa,211 U.S.P.Q. 636(P.O.Bd.App.1978), ACS Hospital Systems, Inc. v. Montefiore Hospital,732 F.2d 1572,221 U.S.P.Q. 929(Fed.Cir.1984), In re Gordon,733 F.2d 900,221 U.S.P.Q. 1125(Fed.Cir.1984), Lear Siegler v. Aeroquip Corp.,733 F.2d 881,221 U.S.P.Q. 1025(Fed.Cir.1984) and Diversitech v. Century Steps,850 F.2d 675,7 U.S.P.Q.2d 1315(Fed.Cir.1988)).

To support a finding of obviousness based on a single reference, the single reference must suggest the desirability of modifying it's disclosure as needed to accomplish the invention (see In re Gordon,733 F.2d 900,221 U.S.P.Q. 1125(Fed.Cir.1984), Schneck v. Gordon,713 F.2d 782,218 U.S.P.Q. 699(Fed.Cir.1984) and Cooper v. Ford,748 F.2d 677,223 U.S.P.Q. 1286(Fed.Cir.1984)).

To set forth a prima facie obviousness case, evidenced motivation most be provided indicating why one skilled in the art would be motivated, lead, or suggested to modify an existing

reference in view of another reference. In addition, is also improper to base a rejection on the claimed feature being merely a design choice. See *In re Garrett*, 1986 Pat. App. LEXIS 8 (Bd. Pat. App. 1986), where the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences ("Board") specifically stated: "the examiner has not presented any line of reasoning as to why the artisan would have been motivated to so modify the...structure, and we know of none. The examiner's assertion...that the proposed modification would have been "an obvious matter of engineering design choice well within the level of skill of one of ordinary skill in the art" is q conclusion, rather than a reason." Similar discussions can be seen in *In re Chu*, 36 USPQ2d 1089 (Fed. Cir. 1985).

The Examiner bears the initial burden of establishing a prima facie case of obviousness. See In re Rilckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A prima facie case of obviousness is made by presenting evidence that the "reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the references before him to make the proposed substitution, combination or other modification." In re Lintner, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972); In re Lalu, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1984). It is incumbent on the Examiner to state how and why the teachings of the references would have been combined. "If examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent." In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

Any reference used to reject a claim must itself be enabling for the subject matter of the invention alleged to be taught (see In re Wilder,429 F.2d 447,166 U.S.P.Q. 545(C.C.P.A. 1970) and In re Collins,462 F.2d 538,174 U.S.P.Q. 333(C.C.P.A. 1972)).

It is inappropriate to rely on general principles of engineering or physics or common understanding to fill in the gaps in the teachings of a reference (see Panduit v. Dennison,774 F.2d 1082,227 U.S.P.Q. 337(Fed.Cir.1985) and Akzo v. Dupont,810 F.2d 1148,1 U.S.P.Q.2d 1704(Fed.Cir.1987)).

Factors to be considered in determining that claims are not obvious include unexpected results, new features, solution of a different problem and novel properties (see In re Wright,848 F.2d 1216, 6 U.S.P.Q.2d 1959(Fed.Cir.1988)).

The fact that the prior art teaches away from an invention is evidence that the invention is not obvious (see Akzo v. USITC,808 F.2d 1471,1 USPQ2d 1241(Fed.Cir.1986) and In re Graselli,713 F.2d 731,218 USPQ 769(Fed.Cir.1983)).

"We have noted elsewhere, as a "useful general rule," that references that teach away cannot serve to create a prima facie case of obviousness. In re Gurley, 27 F.3d 551, 553, 31 USPQ 2d 1130 (Fed. Cir. 1994). If references taken in combination would produce a "seemingly inoperative device," we have held that such references teach away from the combination and thus cannot serve as predicates for a prima facie case of obviousness. In re Sponnoble, 405 F.2d 578, 587, 160 USPQ 237, 244, 56 C.C.P.A. 823 (1969) (references teach away from combination if combination produces seemingly inoperative device); see also In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984) (inoperable modification teaches away)." (see McGinley v. Franklin Sports Inc., 60 USPQ 2d 1001, 1010 (Fed. Cir. 2001)

Hindsight cannot be used in determining the issue of obviousness and the reviewer must view the prior art without reading into that art the teachings of the application or patent (see Kalman v. Kimberly Clark Corp.,713 F.2d 760,218 U.S.P.Q. 781(Fed.Cir.1983)).

"[T]he best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references . . . . Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight." In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher (see W.L. Gore & Associates, Inc. v. Garlock, Inc., 220 USPQ 303, 312-13 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984))

An assertion that the modification or feature is an obvious matter of design choice is an unsupported conclusion and not a valid basis for the rejection of a claim (see In re Garrett, 33 BNA PTCJ 43 (U.S.P.T.O.Bd.App.Nov. 13,1986)).

All of the limitations in the claim must be addressed. See In re Wilder, 429 F.2d 447, 450, 166 USPQ 545, 548 (CCPA 1970) ("every limitation positively recited in a claim must be given effect in order to determine what subject matter that claim defines"); In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970) ("All words in a claim must be considered in judging the patentability of that claim against the prior art.").

To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill in the art (see Continental Can Co. v Monsanto Co., 948 F.2d 1264, 20 USPQ2d 1746 (Fed.Cir. 1991)).

Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient (see In re Olerich, 666 F.2d 578, 212 USPQ 323 (CCPA 1981))

According to 37 C.F.R. § 1.56.b.2.ii (emphasis added):

> A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

According to Black's Law Dictionary (5th ed.), a "preponderance of evidence" is "Evidence which is of greater weight or more convincing than the evidence which is offered in opposition to it; that is, evidence which as a whole shows that the fact sought to be proved is more probable than not."

B. The Rejections Under 35 USC § 112

In the final Office Action, the Examiner rejects claim 33 under 35 USC § 112, first and second paragraphs. Claim 33 recites "without a ported nozzle." The Examiner asserts that the specification and drawings do not teach this limitation. However, as mentioned previously, the Background of the Invention, page 4, lines 1-5 of the application, as filed, provides:

> Together these form all sides of the housing within a sterilization-sealing station, a ported nozzle is positioned between the top and bottom webs for selective movement of gases into and out of the housing. Upon the evacuation of at least some of the air from the housing via the ported nozzle, steam is introduced into the housing through the ported nozzle.

This portion of the application indicates that a ported nozzle was used to inject gas. It provides antecedent basis for "a ported nozzle."

The paragraph bridging pages 4 and 5 of the application provides:

> While the form, fill and seal process has advantages over the chamber sterilization process, there is room for improvement. In the form, fill and seal process, steam is injected onto a cold article through a nozzle. The steam may condense on the article, thereby causing water spots when dried. If the steam

> condensation is large enough, the package can fill up with water. The nozzle significantly increases the cost of the form, fill and seal equipment.

This paragraph indicates that the ported nozzle caused problems. It provides support for "without."

> In the Detailed Description of the Preferred Embodiments, page 15, lines 6-8 provides:
>
> For the purpose of gas injection, pins 600 are provided within the side walls 425 of seal die 424. The side walls 425 located to the front, back, left and right of the sterilization-sealing station 410 are shown in various drawings.

When read, in view of the drawings, this portion of the application indicates that the inventor proposes to use pins 600, not a ported nozzle, to inject gas.

The gas injection system of the present invention and gas injection pins are described in painstaking detail. In fact, Figs. 7A-7D of the application provide close-ups showing exactly how the gas injection pins function. Throughout the drawings, which would seem to cry out for a ported nozzle if one were used, no mention is made of a ported nozzle. See Ex parte Parks, 30 U.S.P.Q.2d 1234 at 1236. The Board should follow its Ex parte Parks reasoning and conclude "without a ported nozzle" has sufficient antecedent basis.

In the final Office Action, the Examiner takes the position that the term "ported nozzle" can be read on the gas injection pins disclosed in the present application. Applicant recognizes that claims should be given their broadest reasonable interpretation for the purposes of prosecution. However, this interpretation is not reasonable. As described above, the specification teaches that gas injection pins should be used instead of a ported nozzle. Thus, gas injection pins are not the same as a ported nozzle.

To understand the definition of "ported nozzle," one of ordinary skill in the art would look to the form, fill and seal device mentioned in the Background of the Invention section. One of ordinary skill in the art would find the inventor's prior U.S. Patent No. 5,749,203, which explicitly defines a ported nozzle as the nozzle 446 shown in Figs. 4A-4F of the '203 patent. If confusion still remained, one of ordinary skill in the art might compare Figs. 4A-4F of the '203 patent with Figs. 5A-5C of the present application. The blatant difference between the drawings of the two cases is that the '203 patent has a ported nozzle 446 and the present application has gas injection pins 600. Based on all of the evidence, it is unreasonable to read "ported nozzle" on the gas injection pins 600. If the application teaches nothing else about the gas injection pins 600, the application teaches that the gas injection pins 600 are not equivalent to a ported nozzle.

Aside from providing exact literal support (case law is clear that literal support is not required), it is difficult to understand how the application could provide better support for "without a ported nozzle."

The Examiner's assertion that "without a ported nozzle" is new matter in violation of 35 USC § 112 is a "hypertechnical application of legalistic prose relating to that provision of the statue." In re Johnson, 558 F.2d 1008 at 1019, 194 U.S.P.Q. 187 at 196 (CCPA 1997). Reversal of the rejections is respectfully requested.

C. The Rejection

1. Pretreating a Medical Article in a Pretreatment Area

a. The Office Action

In the final Office Action, the Examiner rejects claims 1, 4-7, 15 and 18-21 as being obvious over U.S. Patent No. 5,749,203 to McGowan, Jr. The Examiner states:

> With respect to claims 1 and 15, the McGowan reference discloses a device (figure 1, 10) and a method (col. 1, lines 5-9) for article sterilization. Further, the McGowan, Jr. teaches the following: a device to form a housing in a first web (col. 3, lines 27-29), an article loading station (col. 3, lines 25-27), an alignment device (col. 3, lines 38-42), a sterilization-sealing station for sterilizing a medical article inside the housing (col. 3, lines 53-55), and sealing the medical article within the housing (col. 4, lines 5-9). In addition the McGowan reference teaches that it is known in the art of sterilizing medical articles to precondition such articles in a pretreatment area by applying steam (col. 1, lines 28-34) prior to sterilizing them. Thus, it would have been obvious to one having ordinary skill in the art to modify the method and the apparatus of the McGowan reference to include a preheating step since such a step results in increasing the sterilizing effects of ethylene oxide (col. 1, lines 36-44).

b. The Prior Art vs. The Claimed Invention

Just as the present application discloses three sterilization techniques, the '203 patent, the inventor's previous patent, discloses three sterilization techniques. First, a chamber sterilization process is described from column 1, line 27 through column 2, line 31. Second, a process known as the Anderson Steri-Jet™ process is described at column 2, lines 32-65. The drawbacks of the chamber sterilization process and the Anderson Steri-Jet process are described from column 2, line 66 through column 3, line 15. Third, the '203 patent describes a form, fill and seal process from column 3, line 18 through the remainder of the reference.

The Examiner relies on the third technique of the '203 patent, the form, fill and seal

process, for all claim limitations except for the pretreatment limitation. For example, independent claim 1 recites a sterilization sealing station where the first web and the second web, with the medical article loaded into the housing are sterilized. The Examiner cites column 3, lines 53-55 (the third process) for this limitation. The Examiner cites the first technique for the claimed pretreatment. Earlier in prosecution, it appeared the Examiner believed that the pretreatment disclosure of the first technique also applied to the third technique, the form, fill and seal process. It appears the Examiner's initial confusion has been eliminated. However, it is important for the Board to recognize that the first and third techniques are different and the teachings of one technique do not apply to the other.

The '203 patent describes that the first process, the chamber sterilization process, included pretreatment. Column 1, lines 26-28 of the '203 patent describe the phases of the chamber sterilization process as follows:

> Traditionally, the chamber sterilization process includes four phases: (i) preconditioning, (ii) sterilization (iii) degassing, and (iv) quarantining. In the preconditioning phase, the medical articles to be sterilized are first palletized and then placed in a preconditioning room. The temperature and the humidity in this chamber are set generally between 100°F to 140°F and between 40 to 80% relative humidity.

Thus, the "traditional" process used preconditioning. U.S. Patent No. 5,749,203 to McGowan, Jr. teaches away from a pretreatment area. In the Background of the Invention, column 1, lines 36-45 of the '203 patent provides:

> The purpose of the preconditioning phase is to elevate the temperature and relative humidity of the palletized articles. At these elevated temperatures, ethylene oxide gas is **thought to be** more molecularly active and therefore performs more effectively as a sterilizing agent. Additionally, in the presence of higher relative humidity levels, ethylene oxide is thought to flow more freely through packaging compositions and materials used in forming the articles which are undergoing sterilization (emphasis added).

This portion of the reference relates to the first process described in the '203 patent, the chamber sterilization process. This portion of the reference indicates that a preconditioning phase was used based on a once-had belief that ethylene oxide gas performed better at elevated temperatures. The Examiner questions whether "thought to be" indicates a thought that *was* (past tense) had. The past tense implication is appropriate at least because (i) the statement appears in the Background of the Invention section and (ii) the process is criticized as discussed below.

The paragraph bridging columns 2 and 3 of the '203 provides (with emphasis added):

> While the above described process[es] are effective for sterilizing surgical articles, both processes have several drawbacks. One such drawback in is the length of time required for each of these processes. Another drawback is the concentration of ethylene oxide used during the sterilization phases. At these concentrations of ethylene oxide, generally from between about 400 mg/l to about 1500 mg/l, safety concerns stemming from both toxicity as well as flammability issues are ever present.

This portion of the reference indicates that the chamber sterilization process is problematic because they require too much time. In the final Office Action, the Examiner states "the phrase 'too much time' is a subjective term that varies from one person skilled in the art to another and is not a teaching applying neither [sic.] the pretreatment concept nor a drawback." This is not correct. If the '203 patent stated that the process required five hours, it would be subjective whether five hours is not enough time, the correct amount of time or too much time. The '203 patent goes beyond stating a time. The '203 patent teaches that the chamber sterilization process requires too much time. Clearly, this is not a compliment. It does not matter that people might disagree with whether too much time is required. The important thing is what did the author of the '203 patent think. The author of the '203 patent thought this was a drawback.

A common way to read a patent is to read about the old way, read about the problems with the old way, read about the new way, compare the old way with the new way, and then deduce what was subtracted from or added to the old way to achieve the new way. From this reading, one can conclude that because of the problems with the old way, the addition or subtraction should be made.

Column 3, line 17 through column 4, line 28 of the '203 patent describes how time is saved. With the form, fill and seal process, "a sterilizing gas is introduced . . . into the housing", "the closed housing is then conveyed to a degassing area," and "upon degassing, the housing is conveyed to a quarantine area." See column 3, lines 55 and 56 and column 4, lines 17, 22 and 23. Of the five phases of the chamber sterilization process (first technique), pre-conditioning is eliminated and this saves time. The '203 patent teaches away from preconditioning.

The inventor recognized that there are drawbacks associated with the '203 patent. The inventor realized that there may be some truth in the once-had belief that ethylene oxide gas is more active at elevated temperatures. The inventor therefore proposed to use preconditioning. Perhaps the Examiner believes that using preconditioning is an insufficient inventive step. However, the '203 patent in no way teaches to use preconditioning. Only the present application

teaches to use preconditioning. Any belief that preconditioning is suggested by the '203 patent is hindsight, relying upon what was learned from reading the present application.

Any rejection of the claims relying on the '203 patent for pretreatment should be withdrawn.

2. Gas Injection Pins

a. The Office Action

Independent claims 8 and 12 refer to gas injection pins to inject gas. The Examiner relies upon the Multivac Packaging Machine reference for this limitation. In the final Office Action, the Examiner states:

> With respect to claim 8, 22 and 33, McGowan reference discloses a device (figure 1, 10) and a method (col. 1, lines 5-9) for article sterilization including the following: a device to form a housing in the first web (col. 3, lines 27-29), an article loading station (col. 3, lines 25-27), an alignment device (col. 3, lines 38-42), a sterilization-sealing station where the article is sterilized by injecting gas between the first and second webs using injection nozzles (figure 4D), and then sealing the housing (col. 4, lines 5-9). However, McGowan reference fails to teach injecting gas by using pins. The disclosure of the Multivac Packaging Machines teaches injection by using pins (advantages column). Thus, it would have been obvious to one having ordinary skill in the art to modify McGowan reference method and device to include gas injection pins in order to eliminate small cracks between webs of film where air can enter packages along with gas are eliminated (column 1, lines 5-10).

b. Prior Art vs. the Claimed Invention

First, it should be noted that the Multivac Packaging Machine reference was provided to the Examiner with annotations made by the inventor and others. These annotations are not part of the reference.

Second, it is interesting that in rejecting claim 33, the Examiner asserts that "ported nozzle" reads on the gas injection pins disclosed in the present application. However, in rejecting independent claims 8 and 12, the Examiner admits that the claimed "gas injection pins" do not read on the ported nozzle disclosed in the '203 patent.

There are numerous differences between the system proposed in the reference and that proposed by the inventor.

As the title indicates, the Multivac gas injection pins are used for gas flushing. Gas flushing is when one gas is replaced with another gas. For example, if a bag contained food and

air, the pins could be used to inject carbon dioxide into the bag until a substantial portion of the air were displaced. In this manner, the color and taste of the food may be preserved.

On the other hand, gas displacement is not necessary in the '203 patent. Column 9, lines 32-37 of the '203 patent describes that the chamber is evacuated. Oxygen is removed from the chamber without a gas flushing process. Column 10, lines 1-46 of the '203 patent describes how the evacuation is performed. Referring to Fig. 4B, after a lid 418 and a seal die 424 are secured together, three chambers are formed. These chambers are represented with the letters A, B and C in Fig. 4B. The chambers A and C are evacuated respectively through ports 420 and 428. Chamber B is evacuated through port 448 in nozzle 446. With the evacuation, there is substantially no need for gas displacement, flushing, as proposed by the Multivac reference.

Page 3, column 1 of the Multivac reference describes typical applications to be packaging for red meats, sausage, pork, poultry, fish, cheese, bakery products and fruits and vegetables. On the other hand, the '203 patent is directed to a very different application, namely sterilization of medical articles.

It appears that the Examiner is using prohibitive hindsight in making the rejection. As mentioned above, the '203 patent discloses a nozzle 446 and a port 448. Is the Examiner proposing that it would have been obvious to use the Multivac pins in addition to the nozzle 446? Alternatively, does the Examiner propose to use the pins instead of the nozzle 446? If the Examiner proposes to eliminate the nozzle 446, where is the motivation for doing this.

The Examiner asserts that it would have been obvious to incorporate the teachings of the Multivac Packaging Machines reference into the '203 patent "in order to eliminate small cracks between webs of film where air can enter packages along with gas are eliminated." Initially, we should keep in mind that what we are discussing here is something that one would read that would prompt one to change the device disclosed in the '203 patent to meet the requirements of the claims, based on the teachings of the Multivac Packaging Machines reference.

The statement cited by the Examiner, to the extent it is comprehensible, will now be discussed. First, let's review whether it is reasonable to believe that the Examiner's proposed modification would "eliminate small cracks between webs of film where air can enter the packages." Although the claims are not restricted what is disclosed in the specification, Figs. 6 and 7A-7D demonstrate many pins being positioned between the first and second webs. Figs. 4A-4E of the '203 patent show only one opening. Column 11, lines 34-48 of the '203 patent

describes the sealing process. In the '203 patent, it appears that some sort of melting and heat sealing occur between the first and second webs. The material for the first and second webs is described in the '203 patent at column 8, line 61 through column 9, line 23. As described at column 9, lines 7-10 of the '203 patent, "It is desirable that the top and bottom web forming materials be suitable for the bonding or fusing together portions thereof by a heating source, such as a heat bar or other conventional bonding or fusing sources." One having ordinary skill in the art would not predict any sealing problem in the '203 patent. One having ordinary skill in the art would certainly would not think that gas injection pins would solve any supposed sealing problem.

The Board is requested to note that the '203 patent shows a single ported nozzle between the first and second webs, whereas the Multivac Packaging Machines reference discloses many injection pins between the first and second webs. It seems that small cracks between webs (if they existed) would be caused by the use of brittle materials. In this case, cracks could be eliminated by using more pliable materials for the first and second webs. It does not appear that positioning many gas injection pins between the two webs, instead of positioning a single ported nozzle between the two webs would solve a supposed crack problem.

The Examiner asserts that switching from a ported nozzle to gas injection pins would "eliminate small cracks between webs of film where air can enter packages along with gas are eliminated." The text referring to the elimination of gas is not understood. Does it mean that the elimination of gas is good or that the elimination of gas is bad?

Let's assume that the Examiner means switching from a ported nozzle to gas injection pins will stop gas from being eliminated. However, the '203 patent teaches that gas elimination is necessary and important. For example, the '203 patent describes throughout that the articles cannot be sold until the ethylene oxide concentration decreases to a prespecified low concentration. To accomplish this, the '203 patent describes degassing and quarantine processes. If the gas dissipated more slowly, the process would require more time. The '203 patent describes that a quicker process is desired. Accordingly, the '203 patent teaches away from doing anything that would lengthen the process. If switching from a ported nozzle to gas injection pins would slow the dissipation of ethylene oxide and lengthen the time required for the process, then the '203 patent teaches away from the substitution.

The present invention, not the prior art, suggests using pins instead of a nozzle. There is no motivation to make the changes suggested by the Examiner. Any rejection of the claims that

relies upon the Multivac reference for the claimed gas injection pins, should be withdrawn.

D. Conclusion

It is submitted that the Examiner has not made a prima facie case of obviousness by preponderance of the evidence and reversal of the rejection is requested.

Respectfully submitted,

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Claims Appendix

Claims 1-36 are involved in the appeal are set forth below. Withdrawn and pending claims 1-36 are not set forth below as they are not involved in the appeal.

1. A medical article sterilization device comprising:

a pretreatment area for medical articles, the pretreatment area having a heat source to heat the medical articles;

a device to form a housing in a first web;

an article loading station where a medical article heated in the pretreatment area is loaded into the housing in the first web;

an alignment device to align a second web with the first web; and

a sterilization-sealing station where the first web and the second web, with the medical article loaded into the housing are sterilized and then the first and second webs are sealed together.

2. A medical article sterilization device according to claim 1, wherein the sterilization-sealing station further comprises gas injection pins to inject gas into the housing, between the first and second webs.

3. A medical article sterilization device according to claim 2, wherein the sterilization-sealing station further comprises a steam source to inject steam into the housing, between the first and second webs.

4. A medical article sterilization device according to claim 1, wherein the sterilization-sealing

station further comprises a steam source to supply steam to the housing.

5. A medical article sterilization device according to claim 1, wherein:

substantially no moisture is supplied to the medical articles at the sterilization-sealing station, and

the pretreatment area has a steam source to supply moisture to the medical articles.

6. A medical article sterilization device according to claim 5, wherein:

the sterilization-sealing station comprises a vacuum source and a controller,

the vacuum source evacuates the housing,

evacuating the housing removes moisture from the medical articles, and

the controller maintains the pressure in the housing so as to allow some moisture to remain with the medical articles.

7. A medical article sterilization device according to claim 6, wherein the controller maintains the pressure in the housing so as to allow the relative humidity in the housing to be at least 40 % during sterilization gas exposure.

8. A medical article sterilization device comprising:

a device to form a housing in a first web;

an article loading station where a medical article is loaded into the housing in the first web;

an alignment device to align a second web with the first web; and

a sterilization-sealing station where the first web and the second web, with the medical article loaded into the housing are sterilized and then, the first and second webs are sealed together, the sterilization-sealing station comprising gas injection pins to inject gas into the housing, between the first and second webs.

9. A medical article sterilization device according to claim 8, wherein the sterilization-sealing station further comprises a steam source to inject steam into the housing, between the first and second webs.

10. A medical article sterilization device according to claim 9, further comprising a pretreatment area for medical articles, the pretreatment area having a heat source to heat the medical articles.

11. A medical article sterilization device according to claim 8, wherein the second web is formed of a gas permeable material.

12. A medical article sterilization device according to claim 8, wherein:

substantially no moisture is supplied to the medical articles at the sterilization-sealing station, and

the medical article sterilization device further comprises a pretreatment area having a steam source to supply moisture to the medical articles.

13. A medical article sterilization device according to claim 12, wherein:
the sterilization-sealing station further comprises a vacuum source and a controller,
the vacuum source evacuates the housing,
evacuating the housing removes moisture from the medical articles, and
the controller maintains the pressure in the housing so as to allow some moisture to remain with the medical articles.

14. A medical article sterilization device according to claim 13, wherein the controller maintains the pressure in the housing so as to allow the relative humidity in the housing to be at least 40 % during sterilization gas exposure.

15. A method of sterilizing a medical article comprising:
preheating a medical article in a pretreatment area;
forming a housing in a first web;
loading the medical article heated in the pretreatment area into the housing formed in the first web;
aligning a second web with the first web;
sterilizing the medical article located in the housing and between the first and second webs;
after sterilizing the medical article, sealing the first web to the second web, with the medical article located in the housing and between the first and second webs.

16. A method of sterilizing a medical article according to claim 15, further comprising injecting gas into the housing, between the first and second webs, through gas injection pins.

17. A method of sterilizing a medical article according to claim 16, wherein steam is injected into the housing, between the first and second webs, through the gas injection pins.

18. A method of sterilizing a medical article according to claim 15, wherein steam is injected into the housing, between the first and second webs.

19. A method of sterilizing a medical article according to claim 15, wherein:

sterilization and sealing are conducted at a sterilization-sealing station,

substantially no moisture is supplied to the medical article at the sterilization-sealing station, and

steam is supplied to the medical article at the pretreatment area.

20. A method of sterilizing a medical article according to claim 19, further comprising the steps of:

evacuating the housing at the sterilization-sealing station so as to remove moisture from the medical article, and

maintaining the pressure in the housing so as to allow some moisture to remain with the medical article.

21. A medical article sterilization device according to claim 20, wherein the pressure in the housing is maintained so as to allow the relative humidity in the housing to be at least 40 % during sterilization gas exposure.

22. A method of sterilizing a medical article comprising:

forming a housing in a first web;

loading a medical article into the housing formed in the first web;

aligning a second web with the first web;

injecting gas into the housing, between the first and second webs, through gas injection pins;

sterilizing the medical article located in the housing and between the first and second webs; and

after sterilizing the medical article, sealing the first web to the second web, with the medical article located in the housing and between the first and second webs.

23. A method of sterilizing a medical article according to claim 22, wherein steam is injected into the housing, between the first and second webs, through the gas injection pins.

24. A method of sterilizing a medical article according to claim 23, wherein the steam is

injected into housing to pressurize the housing to a pressure of 60 to 100 psia.

25. A method of sterilizing a medical article according to claim 24, wherein

the housing is evacuated before pressurizing with steam, and

the housing is evacuated after pressurizing with steam and then sterilizing gas is supplied to the housing.

26. A method of sterilizing a medical article according to claim 24, wherein the housing is maintained in a condition pressurized with steam for a time period of 1 to 8 minutes.

27. A method of sterilizing a medical article according to claim 24, wherein

the housing is pressurized with steam and supplied with sterilizing gas within a form, fill and seal device having a sterilization-sealing station, which has an interior volume to contain the housing, and

the housing is pressurized with steam to deliver 10 to 50 Btu of heat per cubic foot of interior volume.

28. A method of sterilizing a medical article according to claim 22, wherein the second web is formed of a gas permeable material.

29. A method of sterilizing a medical article according to claim 23, further

comprising preheating the medical article in a pretreatment area.

30. A method of sterilizing a medical article according to claim 22, wherein:

sterilization and sealing are conducted at a sterilization-sealing station,

substantially no moisture is supplied to the medical article at the sterilization-sealing station, and

moisture is supplied to the medical article as steam at a pretreatment area.

31. A method of sterilizing a medical article according to claim 30, further comprising the steps of:

evacuating the housing at the sterilization-sealing station so as to remove moisture from the medical article, and

maintaining the pressure in the housing so as to allow some moisture to remain with the medical article.

32. A medical article sterilization device according to claim 31, wherein the pressure in the housing is maintained so as to allow the relative humidity in the housing to be at least 40 % during sterilization gas exposure.

33. A form-fill-and-seal medical article sterilization device comprising:

a device to form a housing in a first web;

an article loading station where a medical article is loaded into the housing in the first web;

an alignment device to align a second web with the first web; and

a sterilization-sealing station where the first web and the second web, with the medical article loaded into the housing are sterilized and then the first and second webs are sealed together,

wherein gas is injected between the first and second webs without a ported nozzle positioned between the first and second webs.

34. A form-fill-and-seal medical article sterilization device according to claim 33, further comprising a pretreatment area for medical articles, the pretreatment area having a heat source to heat the medical articles before loading into the housing in the first web.

35. A form-fill-and-seal medical article sterilization device according to claim 34, wherein the sterilization sealing station comprises gas injection pins to inject gas into the housing, between the first and second webs.

36. A form-fill-and-seal medical article sterilization device according to claim 33, wherein the sterilization-sealing station comprises gas injection pins to inject gas into the housing between the first and second webs.